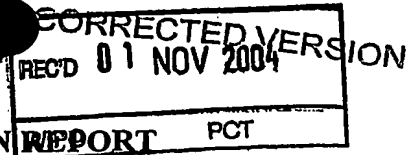


PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference 503958/142	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/NZ2003/000111	International Filing Date <i>(day/month/year)</i> 4 June 2003	Priority Date <i>(day/month/year)</i> 4 June 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ C07K19/00, C07K14/00, C07K 014/315, C07K 016/12; A61K 035/74, A61K39/00, A61K 039/09, A61K39/39; C12N 001/20, C12N15/31; C07H 019/00; C12Q 001/68		
Applicant AUCKLAND UNISERVICES LIMITED et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

- | | | |
|------|-------------------------------------|---|
| I | <input checked="" type="checkbox"/> | Basis of the report |
| II | <input type="checkbox"/> | Priority |
| III | <input type="checkbox"/> | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| IV | <input type="checkbox"/> | Lack of unity of invention |
| V | <input checked="" type="checkbox"/> | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| VI | <input type="checkbox"/> | Certain documents cited |
| VII | <input type="checkbox"/> | Certain defects in the international application |
| VIII | <input checked="" type="checkbox"/> | Certain observations on the international application |

Date of submission of the demand 7 November 2003	Date of completion of the report 20 September 2004
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer D.A. LALLY Telephone No. (02) 6283 2533

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 1 to 24	YES
	Claims nil	NO
Inventive step (IS)	Claims 1 to 24	YES
	Claims nil	NO
Industrial applicability (IA)	Claims 1 to 24	YES
	Claims nil	NO

2. Citations and explanations (Rule 70.7)

- **Document 1:** Fraser, J.D. *et al*: Journal of Immunology, (1 September 2002) 169 (5) 2561-9. "The bacterial superantigen streptococcal mitogenic exotoxin Z is the major immunoactive agent of *Streptococcus pyogenes*".
- **Document 2:** Proft, T. *et al*: Journal of Experimental Medicine, (15 May 2000) 191 (10) 1765-76. "The Streptococcal Superantigen SMEZ Exhibits Wide Allelic Variation, Mosaic Structure, and Significant Antigenic Variation".
- **Document 3:** Arcus, V.L. *et al*: Journal of Molecular Biology, (26 May 2000) 299 (1) 157-68. "Conservation and Variation in Superantigen Structure and Activity Highlighted by the Three dimensional Structures of Two New Superantigens from *Streptococcus pyogenes*".
- **Document 4:** Proft, T. *et al*: Journal of Experimental Medicine, (4 January 1999) 189 (1) 89-101. "Identification and Characterisation of Novel Superantigens from *Streptococcus pyogenes*".
- **Document 5:** WO 02/45739 A1 (Auckland Uniservices Limited), 13 June 2002.

None of Documents 1 to 5 either read alone or in combination with any other document teaches nor suggests any aspect of the invention claimed, rendering all claims both novel and inventive.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The term "does not include a fully functional T-cell receptor binding site" is not properly supported by the description.